



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:) Attorney Docket No.
Timo Kars van den Berg et al.) 080743235001
Serial No.: 10/007,275)
Filed: October 26, 2001)
For: METHOD FOR INHIBITING CELL)
FUNCTIONING FOR USE IN ANTI-)
INFLAMMATORY AND ANTI-)
TUMOR THERAPIES)
Examiner: Yaen, Christopher H.)
Group Art Unit: 1642)
Confirmation No.: 5284)

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REMARKS

Claims 1, 3-8 are in the application as claims 2, 9 and 10 have been cancelled and claims 11-14 have been withdrawn.

Minor editorial amendments have been made to paragraphs 0027 and 0029 in the specification.

Claims 1-10 have been rejected under 35 USC section 112 for various reasons as set forth in numbered paragraphs 4-12 of the Office Action. For convenience, the Examiner's comments will be addressed in the same order as in the Office Action.

In paragraphs 4-6 of the Office Action, the Examiner states that it is unclear which "function" is intended to be interfered with and thus, the boundary of the terms "inhibiting cell functioning" or "inhibits the function," cannot be determined. In response, reference is made to claim 1 where it is stated that the inhibiting function is "of pathologic myeloid cells", and an example of such cells is "macrophages." This is explained in both the specification and also in

claim 2. The limitations of claim 2 have now been incorporated in claim 1 so that this rejection is believed to be obviated.

The Examiner also states the term "drug" is indefinite, apparently for being overly broad. This rejection is not understood since the term "drug" is a well known word. A drug always comprises in addition to an active ingredient ("substance") a usual carrier and adjuvants. The term "drug" is intended to be broad although the limitations immediately following this term provides sufficient and necessary information to one skilled in the art as to the type of drug.

With regard to paragraphs 7 and 8, the Examiner states that the term "substance" is apparently too broad. Again, this rejection is not understood since the term "substance" is intended to be broad and is defined by the phrase that is preceded by the word "substance" in claim 1. See also paragraph 0011 of the specification where the term "substance" is further defined. A person skilled in the art will easily understand that the term "substance" can be found by determining the specific recognition of SIRP by using the test of Adams et al. and by determining the suppression of the macrophagous activation by performing the macrophage activity test as described in detail in the specification.

No word such as "drug" or "substance" is too broad or indefinite per se. If sufficient limitations are absent from a proposed claim then a proper rejection should be given under sections 102 or 103 based on proper prior art. If the Examiner persists in a rejection under section 112, he is invited to cite case authority denying an applicant the use of a word from a standard dictionary because the word is somehow intrinsically indefinite.

The rejection of the phrase "at least 10" in paragraph 8 is not understood where the Examiner raises the question "is 2X at least 10?" Altering something by a factor of 10 is well

known to any high school student. Applicants' attorney has no idea what is meant by use of the term "2X" in this context.

In paragraph 11, the Examiner is concerned about the recited specific antibody terms, and whether one skilled in the art would be able to distinguish those antibodies from other antibodies. In response, reference is made to monoclonal antibodies ED9 and ED17 which are disclosed in Damoiscaux et al. as fully identified in the specification at paragraph 0024. These are quite specific. Thus, is it not believed that a deposit is required.

In paragraph 12, the Examiner rejects the claims because they do not provide enablement for a method of inhibiting cell functioning. With this position, applicant respectfully disagrees. The specification clearly enables a person skilled in the art to practice the present invention without any undue experimentation.

The Examiner contends that the specification does not disclose how to inhibit "all" types of cellular functions associated with the specified diseases. This observation is respectfully disagreed with. Generally, it is not necessary for a drug to be effective that all type of cellular functions be inhibited. The applicants have shown that the relevant cell functions associated with the diseases concerned, such as the functioning of pathologic myeloid cells is inhibited. In view of the close connection between the inhibition of the functioning of pathologic myeloid cells and the substantial suppression of microphageous activation, there is no reason to doubt the effectiveness of the drug. The results obtained with the FAB-fragments of the monoclonal antibodies ED9 and ED17 are illustrative in this respect.

The term "modified products thereof" is exemplified in the specification at paragraph 0014 and refers to customer modifications of these drugs to improve such features as their

uptake, tolerance, etc., without influencing the intrinsic activity. Further, to go from "in vitro" to "in vivo" is mere acceptable experimentation, well known to those skilled in the art.

In this regard, the Examiner is probably not aware that the applicants here are researchers at a prominent Dutch university and, as such, are involved in cutting edge research.

In view of the above comments, the Examiner is respectfully requested to reconsider the various rejections under section 112 and allow the application to proceed to issue.

Dated: June 27, 2003

Respectfully submitted,



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